

REMARKS

Consideration and entry of this paper, and reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance, or in better condition for appeal.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-63 are pending in this application. Claims 3-5, 8, 9, 11-13, 15, 16 and 18-63 were withdrawn from further consideration. Claim 1 has been amended to recite specific amounts of nodulisporic acid derivative and crystallization inhibitor system and specific solvent, cosolvents, film-forming agents and surfactants of the claimed formulation.

Support for these amendments can be found throughout the specification as filed (see, for example, paragraphs 0615, 0618-0620, 0629, and 0640-0646 of the specification as published).

No new matter has been added.

Applicants thank the Examiner for withdrawing the rejections of the claims under 35 U.S.C. § 102(b) as being anticipated by Meinke *et al.* and Cleverly *et al.*

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

The issues raised by the Examiner in the Office Action are addressed below in the order they appear in the prior Action.

II. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 1, 2, 6, 7, 10, 14, and 17 are rejected under 35 U.S.C. § 103(a) as being obvious over Meinke *et al.* (WO9629073) and Cleverly *et al.* (U.S. Patent Application No. 10/222,559; USAN 2004/0037869). Applicants respectfully traverse in view of claim 1 as amended. The cited references do not render the pending claims obvious.

The Examiner asserts that Meinke teaches a formulation comprising the elected t-butyl nodulisporamide and the liquid carriers such as propylene glycol and that the formulation can be a spot-on formulation. The Examiner also alleges that Cleverly teaches a formulation that can contain numerous pharmaceutical agents including nodulisporic acid derivatives and can be a pour-on formulation. The Examiner further alleges that Cleverly teaches that a formulation can comprise benzyl alcohol and /or polyoxyethylene sorbitan fatty acid esters as crystallization inhibitors. The Examiner concludes that it would have been obvious to one having ordinary skill in the art to combine the cited references to arrive at a formulation as claimed.

Applicants respectfully submit that Cleverly does not meet the criteria to be qualified as prior art under 35 U.S.C. §102 (a)/(b) and (e) rendering the rejection under 35 U.S.C. §103 improper. Cleverly is not available under 102(a) or (b) as its earliest publication was after the effective filing date of the present application.

MPEP § 706.02(k) states that

“[e]ffective November 29, 1999, subject matter which was prior art under former 35 U.S.C. § 103 via 35 U.S.C. § 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention ‘were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.’ This change to 35 U.S.C. § 103(c) applies to all utility design, and plant applications filed on or after November 29, 1999...”

As Cleverly and the instant application are commonly assigned to Merial, it cannot be properly considered as a reference under 35 U.S.C. §103(a), as 35 U.S.C. §102(e) expressly forbids such a reference from “precluding patentability.” This reference is not by “another,” as required by Section 102(e). (The assignment of the present application is set out at Reel 021581, Frame 0615; the assignments of U.S. Patent Application No. 10/222,559 are set out at Reel 014461, Frame 0091 and at Reel 014407, Frame 0837.) Accordingly, it is respectfully requested that the rejection of claims under 35 U.S.C §103(a) as being unpatentable over Cleverly (U.S. Patent Application No. 10/222,559) be withdrawn.

Establishing a *prima facie* case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. The Examiner is respectfully reminded of the case law, namely, that there must be some prior art teaching which

would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). As stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). The Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: “[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727. Furthermore, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Applicants respectfully reiterate that, Meinke does not teach or suggest all the claim limitations. Meinke mentions spot-on formulations only generally as a possible way of applying an active compound to humans and animals to control internal or external parasites (page 34, line 15-21) but does not specify any compositions and any required ingredients and their proportions in such formulations. Meinke does not teach or suggest a crystallization inhibitor system comprising a polymeric film-forming agent and a surfactant. In addition to the arguments of record with respect to this reference, Meinke does not relate to the solvents and cosolvents of the claimed formulations as well as specific amounts of the claimed ingredients. Based on the

teachings of Meinke, one skilled in the art would not be able to derive the spot-on formulations of the pending claims as amended.

For the foregoing reasons, the references cited by the Examiner do not render the claimed subject matter *prima facie* obvious. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

III. THE NONSTATUTORY DOUBLE PATENTING REJECTION IS OVERCOME

Claim 1, 2, 6, 7, 14, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 4 and 5 of copending U.S. Application No. 11/580,731, over claims 1, 8 and 9 of copending U.S. Application No. 12/119,150 and claims 1, 4 and 5 of copending U.S. Application No. 10/826,105 in view of Cleverly (U.S. Patent Application No. 10/222,559, Publication No. US (2004/0037869)). The rejection is respectfully traversed.

Applicants reiterate that the issue of whether there is indeed double patenting is contingent upon whether the instant claims herewith are indeed considered and, if so, whether the Examiner believes there is overlap with the claims ultimately allowed in the instant application and U.S. Patent Application Nos. No. 11/580,731, 12/119,150 and 10/826,105 in view of Cleverly (U.S. Patent Application No. 10/222,559). If, upon agreement as to allowable subject matter, it is believed that there is still a double patenting issue, a Terminal Disclaimer as to the conflicting applications will be considered for the purposes of expediting prosecution.

Accordingly, reconsideration and withdrawal of the double patenting rejection, or at least holding it in abeyance until agreement is reached as to allowable subject matter, are respectfully requested.

REQUEST FOR INTERVIEW

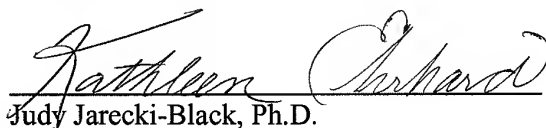
If any issue remains as an impediment to allowance, an interview with the Examiner and SPE is respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

For the reasons stated above, Applicants respectfully request a favorable reconsideration of the application, consideration and entry of this paper, reconsideration and withdrawal of the rejections of the pending claims, and prompt issuance of a Notice of Allowance.

Respectfully submitted,
MERIAL LTD.
FROMMER LAWRENCE & HAUG LLP

By:



Judy Jarecki-Black, Ph.D.

Reg. No. 44,170

Tel. No. (678) 638-3805

Fax No. (678) 638-3350

Thomas J. Kowalski

Reg. No. 32,147

Kathleen N. Ehrhard, Ph.D.

Reg. No. 55,144

Tel. No. (212) 588-0800

Fax No. (212) 588-0500